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POSTSCRIPTS

IN THIS ISSUE:

Official publication of the American Medical Writers Association Pacific Southwest Chapter

POSTSCRIPTS

AIMS AND SCOPE

Postscripts is the official publication of American Medical Writers Association (AMWA) Pacific Southwest chapter. It publishes news, notices, job postings, and articles of interest in all areas of medical and scientific writing and communications. The scope covers clinical and regulatory writing, scientific writing, publication planning, continuing medical education (CME) and physician/patient education, social media, current regulations, ethical issues, medical writing training and certification, and good writing techniques.

MISSION STATEMENT

The mission of *Postscripts* is to facilitate the professional development of medical writers and serve as a tool to advance networking and mentoring opportunities among all members. Towards this mission, *Postscripts* publishes significant advances in issues, regulations and practice of medical writing and communications; skills and language; summaries and reports of meetings and symposia; and book and journal summaries. Additionally, to promote career and networking needs of the members, *Postscripts* includes news and event notices covering AMWA Pacific Southwest Chapter activities.

SUBSCRIPTION: *Postscripts* is published monthly except in January and July. The magazine is available as an open access publication and is currently distributed online only.

INSTRUCTIONS FOR CONTRIBUTORS: We consider articles on any topic of interest to our membership. It is helpful to look at the past December issues for year-end tables of contents, and to browse past issues for style and type of articles published. We welcome contributions from AMWA members. Non-member contributions are generally by invitation by the Editor or any member of the Chapter's Board. Detailed instructions are provided in the December 2015 issue, *Postscripts* 2016;6(48):211.

ADVERTISING: *Postscripts* is an advertising-free magazine. However, articles describing products and services relevant to medical writers, editors and communicators may be considered or solicited. As a service to our members, they may submit advertisements for their services or products for free. Please contact the Editor.

WEBSITES:

Chapter website:	http://www.amwa-pacsw.org
AMWA website:	http://www.amwa.org
Postscripts:	https://archive.org/details/@postscripts
	http://issuu.com/postscripts

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In this issue. . .

COVER:
The Long Room of the Old Library at Trinity College Dublin, Ireland. (via Wikipedia)
https://en.wikipedia.org/wiki/Trinity_College_Library

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https://en.wikipedia.org/wiki/Trinity_College_Library#/media/File:Long_Room_Interior,_Trinity_College_Dublin,_Ireland_-_Diliff.jpg

From the President's Desk

The big news for our chapter is that **registration is open** for the **upcoming 2017 AMWA Pacific Coast Conference**, which will be held at the Crowne Plaza Costa Mesa hotel on April 21-22, 2017. For those of you not familiar with Costa Mesa, it is close to Disneyland and the beautiful coastal towns of Orange County, plus shopping and restaurants at South Coast Plaza. For our conference, we are excited to offer two intensive training sessions that include an editing clinic and a hands on training session for preparing documents for eCTD submission. The conference will also include short session presentations and networking opportunities with a broad variety of medical writing professionals. Other activities include a Saturday evening dinner, followed by a theater night at South Coast Repertory in Costa Mesa. Please visit our chapter web page at http://www.amwa-pacsw.org/2017-pcc.html for more information and a registration link. Be sure to register by February 28 to get the early-bird rate!

We would like to thank everyone who participated in our December 2016 Chapter Member Survey. As we noted in our email of February 5 to the chapter membership, the results indicated that members place a high value on chapter networking events, free chapter webinars, fee-based chapter lunch presentations, and the AMWA National conference. For fee-based webinars, 47% of respondents indicated that $20 and 39% indicated $10 would be a fair price. A majority of respondents (72%) thought that current AMWA dues were priced "just about right."

As promised, in early January 2017 we officially started our chapter mentorship program, and we are proud to announce that we successfully paired seven mentees with mentors. Many thanks again to Michele Vivirito and Jenny Grodberg, our chapter mentorship experts, for providing valuable training for successful mentorship processes, and for helping to guide the program forward to this point. At the request of the AMWA Indiana chapter, we have shared our mentorship webinar training materials with them, and we look forward to hearing about their experiences starting a chapter mentorship program.

Hope you all enjoy your midwinter break for Presidents' Day weekend, and can get out in the sun (or snow) a bit.

Susan

Susan Vintilla-Friedman, MWC

Non Sequitur: Bias in Clinical Research and Communications

Greetings, AMWA Pacific Southwest Chapter members.

As we begin another year of publishing the *Postscripts* newsmagazine, we renew our commitment to sharing educational, entertaining, or intriguing information for—what we set as our mission this time last year— "Becoming a Better Writer." Last February, we reviewed some common rules of good scientific writing by Dmitry Budker, PhD, Professor of Physics at UC Berkeley, such as, "Question each and every statement," and "Read the final draft of manuscript." We now take these rules a little further, continuing our quest to become *better writers*. In this issue, we address bias in clinical research and communications.

Good writing skills demand clear, persuasive flow of text based on bias-free data analyses and presentation. Eliminating bias increases our audience's confidence in the conclusions we draw through our reports and narratives. As medical writers and pharma professionals, we are held at a higher standard than the body politic, and we are expected to deal with *real* facts, not *alternative* facts. Our writings and reports may affect patients' lives. Failure to write clear, precise text can cause ambiguity or, even worse, misunderstanding.

The "little" things aren't so little: Bad punctuation or sloppy word choice can convey bias

As Lynne Truss' classic "Eats, Shoots & Leaves," shows, words (or rather, their meaning) are slaves to punctuation. Commas, apostrophes, colons, and semicolons shape the writer's intent, as Hope Lafferty prods us to pay attention to the "phonetic expression" of punctuation, particularly in professional and scientific writing (page 7, this issue). Hope provides an example:

> "Question marks display the author's frustration. 'Will you please help me with this?' versus 'I would love it if you could help me with this.' reflect different tones. The choice to use a period—or the choice not to use a question mark—changes how we write the sentence. If we want to appear calm and put together, rephrasing a question into a stated request helps convey that sense to our readers."

Word choice also matters in professional writing, particularly with regards to how a study's patient population is described. On page 8 of this issue, Rebecca Anderson recounts an incident from the University of New Hampshire (UNH). In 2013, UNH published an online "Bias-Free Language Guide" designed to increase writers' sensitivity regarding societal labels and disadvantaged groups. However, this initiative had to be scrapped and the guide was yanked 2 years later because, as the UNH president said, "It is ironic that what was probably a well-meaning effort to be 'sensitive' proved offensive to many people, myself included." In the end, everyone agreed that "Caucasians" are not "European-American individuals," and "overweight" are not "people of size," as the guide recommended. We must consider the connotations of our word choices, and being unaware of cultural mores is no excuse. The medical writer's bible, *AMA Manual of Style*, 10th edition, has a complete chapter on "Correct and Preferred Usage," which delineates what's acceptable and what's not in medical writing.

Combating bias in clinical research reporting

A lot of water has flowed under the bridge since Senator Grassley's investigation into the practice of ghostwriting and other unethical practices—by some pharma companies—such as funding continuing medical education programs to promote off-label use of their drugs. Senator Grassley is a ranking member of the US Senate Committee on Finance. His 2010 report "Ghostwriting in Medical Literature" was a *kumbaya* moment for publication professionals in pharma, and it created a surge in efforts toward transparency and codification of ethical and publication practices. ISMPP, AMWA, EMWA, ICMJE, MPIP, and other professional medial writers', editors', and publishers' organizations took the lead by developing position papers and guidelines and by promoting educational initiatives for their members and the public. On page 10 of this issue, Dikran Toroser describes some of these initiatives.

With the floodgates now open, we are witnessing a trend toward more transparency, right down to disclosure of clinical study reports (CSRs) and de-identified patient-level data (see page 14). The availability of raw data may allow researchers to confirm findings reported in the CSRs, and uncover new information.

Statistical tools and improved study design to address clinical research bias

Clinical testing of new drugs is generally first done in a small population of patients (Phase 2) to address potentially efficacious dose range and safety before the drug is tested in a statistically-powered Phase 3 trial. However, Phase 2 trials have poor predictive value of the success of pivotal Phase 3 trials—nearly 45% of the drugs or devices with promise in Phase 2 studies fail in Phase 3. These failures occur across devices, drugs, and biologics; early- and late-stage indications; and regardless of target age group. Each late-stage failure can cost up to a billion dollars to the sponsor.

In the absence of a crystal ball, however, drug developers must use limited data from Phase 2 trials to strike a Faustian bargain, plunging headlong into Phase 3 execution in earnest. Some of these problems arise from inadequate design of Phase 2 trials and the use of different endpoints (eg, surrogate markers in Phase 2 versus clinical outcomes in Phase 3). At least 2 statistical tools have been used to address such bias: power analysis and intention-to-treat (ITT) analysis. Dikran Toroser on page 8 does an excellent job describing these tools in greater detail.

And so, it's back to the drawing board. How can researchers ensure more flexible, more applicable Phase 2 trials? One obvious reason for non-productiveness of Phase 2 trials is that Phase 3 trials are larger and feature a more heterogeneous population that may include sicker patients for whom the Phase 2 dose may not be efficacious (or worse, may be more toxic). Furthermore, "rare" adverse events and safety signals have higher probability to manifest in a larger study group. These issues have led clinical researchers to adopt more flexible approaches than the traditional double-blind, placebo-controlled, parallel group design of the randomized control trial. Such approaches include:

- Randomized selection control trials (also called multi-armed adaptive trials): Multiple treatments are randomized, and the groups with largest effect are green-lighted for further testing. Examples of this paradigm include the I-SPY 2 and FOCUS4 trials. In I-SPY 2, patients with breast cancer that had a specific tumor biomarker signature were randomized to 10 subgroups, each with an experimental and control arm. As the trial progressed, the drug groups with poor responses were dropped, enriching those with better clinical profiles. This approach allows researchers to learn and adapt during the trial.
- Randomized discontinuation designs: This 2-step design involves patients being initially treated with a test compound. Those with stable disease are then randomized to receive either the test compound or the standard-of-care (or placebo).
- "Basket" trials: These test experimental drugs on patients who have different types of cancer but the same genetic mutation. This is one way to perform trials in rare cancers without running big risky trials for one cancer type.

Conclusions

Bias can only be addressed if one recognizes its existence. The moment a new drug enters the human testing stage, biases are present in study design, data analysis, and data is presentation.

Reducing bias at every level of drug development is another way to increase the predictive value of early trials and to increase the validity and credibility of published results.

Acknowledgement

The author thanks Clare Prendergast, MA, for substantive editing of this article.

Sources and further readings:

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Ajay K Malik, PhD
Editor

Praxis

By Hope J Lafferty, AM, ELS, AMWA Southwest Chapter Member

And That Was the End of the Dragon

On December 11, 1972, at 5:50 pm, I fell in love. I was watching the Electric Company on WCNY when my young life changed forever. On screen, in front of a backdrop too dark for children's television, sat Victor Borge with a book in his hand. It wasn't the Clown Prince of Denmark that stole my heart. It was his phonetic expression of punctuation that started my love affair.

It's not everyone that finds true love at age 7. I'll spare you the undulations of how our relationship has evolved over decades of living together. But, I was hoping to spread the love.*

In my trainings, I discuss the appropriate use of punctuation for professional and scientific writing. Knowing how to use the various marks well shows how committed a person is to the craft of writing. On the flip side, incorrect use of punctuation highlights an author's urgency and takes away from her or his otherwise brilliant message.

As my high school band director said, "You can stay quiet and have everyone think you're stupid, or you can open your mouth and remove all possible doubt." I apply this lesson to the use of punctuation in formal, nonliterary writing, which is what my clients typically write. I suggest limiting use to commas, periods, and an occasional parenthesis.

I'll use simple examples from emails that we all have received and have possibly generated. These apply to any type of writing, so stay on the lookout in all your documents.

Question marks display the author's frustration. "Will you please help me with this?" versus "I would love it if you could help me with this." reflect different tones. The choice to use a period—or the choice not to use a question mark—changes how we write the sentence. If we want to appear calm and put together, rephrasing a question into a stated request helps convey that sense to our readers.

Exclamation points overstate the vibe. Take "Thanks!" That exclamation point equals a smiley emoticon, which we wouldn't put in a professional email (would we…). Unless someone just transferred an ungodly amount of money into your savings account, "Thanks," or "Thanks a lot," work just fine. Make sure to sign your name or initials after the comma. "Thanks." can be construed as abrupt and dismissive.

Dashes and hyphens I love, but most people screw them up. Semicolons too. Know your limits. Unless you want to become a real geek about punctuation, avoid them.

The good news is that punctuation and I have an open relationship. I encourage you to use punctuation to shape your writing. Let the marks balance your meaning. When the words are clear and carefully chosen, you don't need the punctuation to help you make your point (just look at texting.)

HOPE J LAFFERTY, AM, ELS, joined AMWA in 2003, currently serves as AMWA's Education Administrator, and will become President of the Board of Editors in the Life Sciences in May 2017. The bulk of her work centers in the academic and research space, and after years of exclusively editing and writing, Hope has stepped out from behind the desk to teach communications skills (scientific [and other] writing, public speaking, and engaged listening) and consult with medical and public health researchers on multiproject grant applications and book proposals. She blogs, meditates, and podcasts out of Marfa, Texas, and looks for any excuse to take a roadtrip. Connect with Hope at hope@hopelafferty.com.

*National Punctuation Day is September 24th.

Taking the Bias Out

By Rebecca J Anderson, PhD, AMWA Pacific Southwest Chapter Member

Given all the rhetoric we've endured during the last election cycle, I'm reminded of the brave folks at the University of New Hampshire. In 2013, a group of faculty, students, and staff associated with the school's diversity office issued a 4,800-word "Bias-Free Language Guide." They had good intentions, and many of their recommendations were already in the mainstream, such as using "black" or "African-American" instead of "negro" or "negroid."

But some of the Guide's other entries raised eyebrows. Here are a few examples and the "bias-free" alternatives the Guide suggested:

- Seniors – people of advanced age
- Poor – person who lacks advantages that others have
- Overweight – people of size
- Homosexual – same gender loving
- Foreigners – international people
- Handicapped – person who is wheelchair mobile

Ok. These are wordy, awkward substitutes, but at least give the authors credit for trying to be respectful of individuals who have often been maligned by an insensitive society.

The Guide also criticized "mothering" and "fathering," cautioning that, like "chairman" and "mailman," speakers must "avoid gendering a non-gendered activity." We all appreciate the progress toward equality for women, but some might debate picking on mothers and fathers. There are certain biological "facts of life" that make it hard to equally distribute child care between men and women—breastfeeding, for example.

The most controversial items, though, were these suggestions:

- Caucasian – European-American individuals
- Healthy – non-disabled
- American – US citizen

The Guide said using "American" as a substitute for US citizen was incorrect, because Canadians and residents of South America are Americans, too. (Ironically, the University of New Hampshire's sports teams, the Wildcats. participate in the ***America*** East Conference.)

Conservative groups pounced, faster than a Russian e-mail hacker. They said the Guide was trying to be ***too*** politically correct. How in the world, they asked, can words like American, healthy, and Caucasian possibly be problematic? You could almost see the stars and stripes spewing out their America-First ears in rage. Remember, these are the same guys who cling to "illegal alien" and "Islamic terrorist" as perfectly ok.

But let's give the right-wingers credit for one thing. They threw a spotlight on a question that all writers struggle with: Just where do we draw the line in our word choices? When do commonly used terms with official dictionary definitions become offensive because of new shades in meaning? Language evolves, and we must evolve with it—forever cognizant of the unofficial, emotionally charged inferences that old words take on, based on new contexts, political and otherwise.

By mid-2015, mockery of the Guide on conservative websites, in the mainstream media, and by the state Republican Party hit a high point, and the UNH president felt compelled to issue a statement. He said the university never forced anyone to follow the Guide's recommendations, adding, "The only UNH policy on speech is that it is free and unfettered on our campuses. It is ironic that what was probably a well-meaning effort to be 'sensitive' proved offensive to many people, myself included."

Shortly afterward, the Guide was removed from the university's website—a shame, really. The Guide was an imperfect tool, but it generated an important conversation—one that Janet Napolitano, President of the University of California, gladly picked up and carried forward.

About the same time that the UNH Guide disappeared, Napolitano's office began sponsoring a series of faculty leadership seminars across the UC system. At the heart of these seminars was a list of menacing "microaggression" terms that the faculty were urged to avoid.

According to the training materials, microaggressions are subtle actions, usually unintentional, that nevertheless perpetuate discrimination against disadvantaged groups, even in environments where overt discrimination has been abolished. Examples include:

- "You speak English very well," because it implies the person is a perpetual foreigner in his/her own country.
- "There is only one race, the human race," because it denies the significance of a person's ethnic or

racial history.
- "Men and women have equal opportunities for achievement," because it implies that if women cannot make it, the problem is with them.

The old nursery rhyme, "Sticks and stones may break my bones, but words will never hurt me," really doesn't hold true. As writers, we know that words matter. The difference between a properly vs improperly chosen word on a patient's chart can literally mean the difference between life and death. Unfortunately, the more nuanced, poor-word choices are harder to spot but are equally harmful, especially when we are addressing readers who have different life experiences than our own.

Writers must constantly remind ourselves that words have great impact, whether they are in an NDA, a Patient Information Sheet, or a 140-character Tweet. I just hope that, in addition to Spell-checker, Grammar, and Thesaurus, Microsoft adds a "microaggression-checker" to its next version of Word, so I can flag my subconscious, unintentional vocabulary flubs.

REBECCA J ANDERSON, PhD, is a freelance medical writer and the author of two books, *Nevirapine and the Quest to End Pediatric AIDS* and *Career Opportunities in Clinical Drug Research*. Prior to medical writing, Dr. Anderson managed research and development projects for twenty-five years in the pharmaceutical/biotech industry. She holds a PhD in pharmacology from Georgetown University. She lives in Southern California, and when she is not writing, she absorbs the sights and sounds of the West Coast's rich culture and heritage. She can be reached at rebeccanderson@msn.com.

AMA-zing Style — The AMA Manual of Style Column

By Dikran Toroser, PhD, CMPP, Amgen Inc., Thousand Oaks, Calif.

Bias in Medical Practice and Medical Publications

Definition of bias: A systematic situation or condition that causes a result to depart from the true value in a consistent direction. Bias often refers to defects in study design (often selection bias) or measurement. One frequently used method to reduce measurement bias is to ensure that the investigator measuring outcomes for a participant is unaware of the group to which the participant belongs (ie, blinded assessment).

Bias exists and is often unwelcome in many spheres of life. It can significantly limit the validity of research when trying to draw conclusions from a study about a research question. Despite much progress, unfortunately, bias is regarded as a continuing potential problem in medicine and also in the medical literature. For example, in 2001, rumors were circulating in Greek hospitals that surgery residents, eager to rack up scalpel time, were falsely diagnosing hapless Albanian immigrants with appendicitis. To determine whether the rumors were founded, a study was carried out by Dr Ioannidis' group (now based in Stanford, CA) to determine whether there were any grounds to these rumors. It turned out that the appendices removed from patients with Albanian names were more than 3 times as likely to be perfectly healthy compared with those removed from patients with Greek names.[1] The lead author was quoted as saying "*it was hard to find a journal willing to publish it, but we did*." Biased or badly designed articles in the medical literature also lead to problems in appraising medical evidence and inappropriately skew the medical literature.

The *AMA Manual of Style* tackles bias in several sections.

Was the hypothesis supported? In properly dealing with bias, whether the hypothesis was supported or refuted by the results should be addressed. The study result should be placed in the context of published literature. The limitations of the study should be discussed, especially possible sources of bias and how these problems might affect conclusions and generalizability.

Evidence to support or refute the problems introduced by the limitations should be provided. The implications for clinical practice, if any, and specific directions for future research may be offered. The conclusions should not go beyond the data.

Publication bias is the tendency of authors to submit and journals to preferentially publish studies with statistically significant results. To address the problem of publication bias, the ICMJE has for some years required, as a condition of publication, that a clinical trial be registered in a public trials registry. The policy defines a clinical trial as "*any research project that prospectively assigns human subjects to intervention or comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome*."

Statistical concepts: Randomized controlled trials often suffer from 2 major complications:
1. noncompliance, and 2. missing outcomes.
Intention-to-treat (ITT) analysis is a statistical concept designed as one potential solution to these problems. It gives an unbiased estimate of treatment effect. ITT includes every subject who is randomized according to randomized treatment assignment. It disregards protocol deviations, non-compliance, withdrawal, and anything else that happens after randomization. In ITT analysis, estimate of treatment effect is generally conservative.

Many arguments against ITT analysis appear to be also valid. Although use of ITT analysis is optimal in trials that test whether one treatment is superior to another, use of such analysis can bias the results of equivalence and noninferiority trials. Thus, in addition to ITT analysis, authors should report results for only participants who completed the trial. Interpretation of the results depends on the confidence interval for the difference between the new intervention and the active placebo.

Addressing Potential Sources of Bias in Industry-Sponsored Studies. Biases are potentially introduced when the authors may have major conflicts of interest, which must all be disclosed. Concerns about potentially misleading reporting of pharmaceutical industry research have sometimes surfaced and, despite tremendous advances in recent years, the credibility of industry-sponsored clinical research has suffered.[2,3] To close a potential credibility gap, professional organizations, including ICMJE, ISMPP, AMWA, and EMWA, as well as the Pharmaceutical industry[3] (PhRMA) are actively working to address selective or biased disclosure of research results, by helping develop guidelines for how to disclose conflicts of interests.[3]

Acknowledgement
Thanks are due to Ajay Malik, PhD, for editorial input.

Also see pages173-4, 838, 841 and 857 of The *AMA Manual of Style* 10th edition.

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DIKRAN TOROSER, PhD, CMPP, a member of the AMWA Pacific Southwest chapter, has been a regular contributor to the *Postscripts* magazine since 2012. He developed the monthly AMA-zing Style column which covers topics from the AMA Manual of Style, and has also written on publication-related topics in these pages. Dikran is currently a Senior Medical Writing Manager at Amgen Inc. in Thousand Oaks, California. He earned his PhD in Biochemistry from Newcastle University (UK), and did his postdoctoral training in biochemical genetics at the John Innes Center of the Cambridge Laboratory (Norwich, UK) and in molecular biology with the USDA. Prior to Amgen, Dikran was on the faculty (research) at the School of Pharmacy at the University of Southern California. He can be reached at dtoroser@amgen.com.

Highlights of Pacemaker December 2016 issue

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PACEMAKER

Access December 2016 issue here:
http://amwancal.org/wp-content/uploads/2016/12/Pacemaker_2016-12.pdf

AMWA Pacific Coast Conference (PCC) 2016

Coverage of the Pacific Coast Conference: Reports Covering 5 Open Sessions.

Session 1: **10 Things Every Medical Writer Needs to Know About Regulatory Publishing**

Speakers:
Stacia Higman, BA, CPIM, Higman Graphics—General Publishing; San Francisco, CA
Caren Rickhoff, BA, MWC, Principal Medical Writing Consultant, MedGraphica Medical Writing Services; Sunnyvale, CA

Report by Nicola Gillespie, DVM

Stacia Higman and Caren Rickhoff used their combined expertise and experience in the pharmaceutical industry to highlight 10 best practices for writers preparing regulatory documents. Working closely with the publisher, asking questions, and establishing expectations early in the writing process can help writers avoid problems at the time of publication.

Session 2: **What You Should Know About Data Transparency and an ICH E3 Update**

Speaker: Nancy Katz, PhD, MWC, President and Principal Medical Writing Consultant, Illyria Consulting Group, Inc.; Soda Springs, CA

Report by Suzanne Canada, PhD

Nancy Katz presented an overview of the history of changes in reporting clinical trial data, the latest of which were proposed in 2016. These changes require de-identified data to be shared on public registries in order to publish the trial results. Of course, over time there has been a trend towards more public access to everything, so it is no surprise that the results of clinical trials—a highly regulated arena—would be subject to the same scrutiny.

Session 3: **LinkedIn: How to Maximize Your Visibility**

Speaker: Andrew Davis, Synergistech Communications; San Francisco, CA

Report by Almas Shabvani

LinkedIn is the world's largest professional network that uses social media as a model. Learn how you can make the most of your LinkedIn account.

Session 4: **PLOS (The Public Library of Science)**

Speaker: Sara Kassabian, MS, Communications Associate at PLOS; San Francisco, CA

Report by Nicola Gillespie, DVM

Social media was in the spotlight at one of the PCC Conference sessions this year. Speaker Sara Kassabian led a lively discussion on the use of Twitter and reddit for sharing science research with the public. She also detailed the history and mission of PLOS (the Public Library of Science), a nonprofit open-access publisher founded in 2001.

Session 5: **Who Goes There? The Need to Define the Profession of Medical Writing**

Speaker: Tom Lang, MA, Tom Lang Communications and Training International

Report by Nicola Gillespie, DVM

Tom Lang believes that we cannot support and promote our professional identity without first adequately defining it. He started the session by asking, "Have we adequately questioned our assumptions about writing?" and finished with his own definition of the profession of medical writing.

Mummies and Medicine

By Carla Johnson, DVM

Travel with the Northern California Chapter as they embark on a journey to ancient Egypt for a tour of the Mummies and Medicine exhibit at San Francisco's Legion of Honor museum.

Word Witch Tutorial

By Maggie Norris, BSc, ELS

Editing and reviewing complex documents often requires that you move to another page or section and then return to the previous insertion point to continue editing. In this tutorial, Maggie explains two quick tricks to move the cursor back to the exact point you moved away from. These techniques are efficient for editing and review meetings, when several busy people are counting on you to make good use of their time

Tax Tips for Freelancers

Speaker: Joshua Cooper, CPA; President, Tax Lovin'—An Accountancy Corporation

Report by Barbara Boughton

Learn how you can take the stress out of taxes and create a "powerful work environment" for accounting work. This accountant and yoga teacher also had helpful recommendations for making the most of your tax deductions, including the home office deduction.

This summary was prepared by Nicola Gillespie, DVM, editor of *Pacemaker* newsletter. Email: pacemaker.editor@amwancal.org.

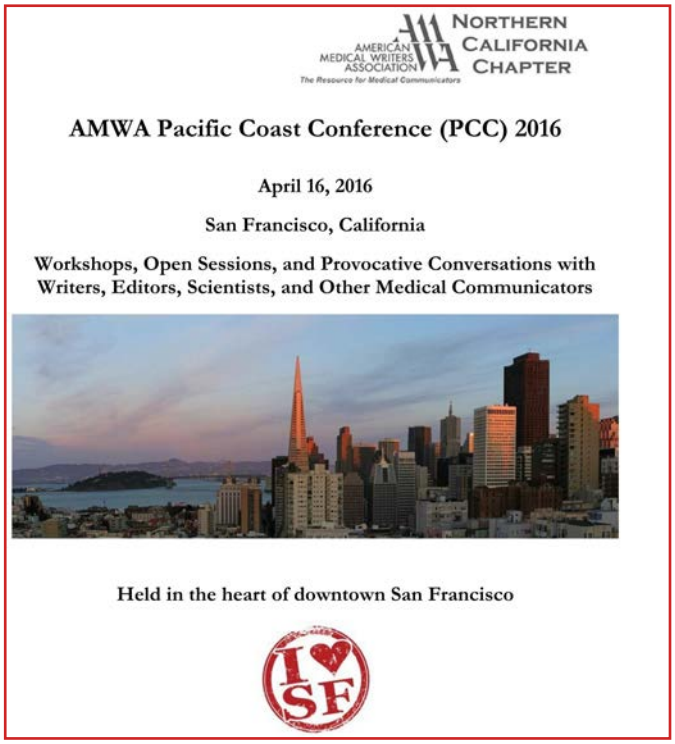
What You Should Know About Data Transparency and an ICH E3 Update*

By Suzanne Canada, PhD, Past President, AMWA Northern California Chapter

Speaker
Nancy Katz, PhD, MWC
President and Principal Medical Writing Consultant, Illyria Consulting Group, Inc.; Soda Springs, CA

Nancy Katz presented an overview of the history of changes in reporting clinical trial data, the latest of which were proposed early this year. These changes require de-identified data to be shared on public registries in order to publish the trial results. Of course, over time there has been a trend towards more public access to everything, so it is no surprise that the results of clinical trials—a highly regulated arena—would be subject to the same scrutiny.

- FDAAA Title III Clinical trial database (2007): This US law requires registration of trials on a public database. This is enforced by penalties for filing false claims, possible loss of grant funding, and public notices of noncompliance.
- NIH Notice of Proposed Rulemaking (2014): This requires clinical trial sponsors to submit results data about unapproved products, and required more patient-friendly information to be disclosed. These provisions are still being implemented
- Institute of Medicine Recommendations on the sharing of clinical trial data (2015): This report makes recommendations on responsibilities, what data should be shared, and how.
- PhRMA and EFPIA joint principles on clinical data sharing (2015): Industry groups support clinical trial data sharing.
- 21 st Century Cures Bill (2015): The US Congress has approved the bill, which states "registered users will be allowed access to de-identified clinical trial data."
- EU Clinical Trials Register: The EU version of the clinical trials register run by the EMA.
- EMA policy 0043: Effective 2010, this policy makes the contents of CSRs available upon request.
- EMA policy 0070: The Policy says that the EMA will disclose the information in CSRs for new MAAs after making a decision; allows redaction of confidential information (implemented in 2015).
- ICJME data-sharing proposal (January 2016): This proposal requires authors to share de-identified individual patient data no later than 6 months after publication. It also requires authors include a data-sharing plan as a component of the clinical trial registration. The WHO issued a statement calling for increased transparency in April 2015, and new EU clinical trial regulations have been rolled after April 2016.



What are the takeaways from all this information?

1. Clinical trial reporting takes a lot of planning: sponsors need to plan for how to share this information.
2. Recognize that CSR information is being viewed publicly and there is a need to manage those expectations of disclosure.
3. Sponsors should establish policies and procedures for managing this requirement, making sure that all information is adequately reviewed and prepared for sharing.
4. We will need to monitor and assess the evolving landscape of public disclosure. Naturally, attendees had a lot of questions about how sponsors would share information anonymously, as this could have a big impact on the expectations and workload of medical writers who work on clinical trials in any context.

SUZANNE CANADA, PhD, is the Communications Committee Chair of the Northern California Chapter and a longtime member of AMWA.

*Reprinted with permission from *Pacemaker*, Decemnber 2016.
Pacemaker, the newsletter of AMWA Northern California Chapter, is available at www.amwancal.org.

The Whole Writer: The Body

By Chip Reuben, MS, AMWA Pacific Southwest Chapter Member

Approaches to Physical Fitness

Let's face it. We writers spend a lot of time at our computers, and excessive inactivity can wear down our bodies physically and mentally. Furthermore, the stress of our work and lives can add to the deleterious effects of unabated office dwelling. Fortunately, moving our bodies physically not only breaks up the inactivity, but also helps to counteract stress. And when it comes to specific approaches, all of them help to some extent. Here are some suggestions:

Avoid elevators and take stairs everywhere, if possible. If you work somewhere that has stairs, use them during your break, or when going to a meeting on another floor of the building. It has been said that an hour of exercise does not make up for 23 hours of inactivity. Doing some stairs will break up the periods of inactivity, and may actually help you do your work, as your brain will not stop working. In fact, Albert Einstein would go play the violin when he was stuck on a physics problem. When you return to your desk, you will not only feel refreshed but may also find you have come up with a solution to a problem you were working on earlier, as Einstein obviously did.

Standing desk. Ask for a standing desk at work, or buy one if you work from a home office. The ergonomic and human resources professionals are recognizing the health benefits of standing desks, and are willing to approve necessary funds. Make sure that the desk is adjustable—nobody can stand and write for 8 hours. These desks can be pricey if you're working from a home office, but they are a great investment in your health. Alternatively, there are many DIY solutions, starting with an upside-down milk crate on your computer desk!

Walk and breathe deeply. If you do not have access to stairs you can always just walk. And whatever you do, be sure to focus on breathing deeply. Deep breathing causes the gas exchange in your lungs to be more efficient as compared with that during shallow breathing, as the proportion of dead space in the lungs is correspondingly decreased relative to the maximum inspired volume. Also, deep breathing increases the responses of the stretch receptors in your lungs that regulate your heart rate. In fact, the action of a simple cough can actually help to counteract transient irregularities in cardiac function, such as, arrhythmias. Also, improved oxygenation of the blood could help you with those work- and life-related problems, as brain function is highly oxygen-dependent.

Be the weekend warrior. If you've gotten to the end of the day or week without having engaged in any meaningful physical activity, it is never too late. You can still hike a mountain, run a marathon, ride your bike to the next town, or take that martial arts class. But don't forget to stretch your muscles first, as long periods of inactivity can leave your muscles stiff, and you could end up with an injury. The more you push your physical performance level, the greater the proportion of anaerobic metabolism, and the more of that "runner's high" you will get. You will also feel great when you return to work on Monday morning. The muscle soreness from the lactic acid deposits will not only remind you that you did the right thing over the weekend, but will also help you burn extra calories as you pay down the metabolic debt.

Be the weekend explorer. There is nothing that says you need to take your weekend physical activity to an extreme. You could simply explore the upcoming flower bloom after all the rain; don't forget your camera! Make your own YouTube video instead of loafing around watching others' video work. There are other places to explore, such as, the farmer's market, a neighborhood park, local trail or beach, but never a mall. *Going shopping is not exploring.*

Disclaimer: The author of this article is not a medical doctor, and this article is not intended to be medical advice. Please contact a qualified health care practitioner for any medical or health-related concerns or conditions.

Acknowledgement
Many thanks are due to Ajay Malik, PhD for helping to concept this article series, and for editing.

CHIP REUBEN, MS, whose artwork forms our Chapter's banner (see the journal's masthead page), is a senior medical/scientific writer with over a decade of experience in regulatory and scientific writing and editing, analyzing data, cutting-edge medical education, and publication development. Visit his LinkedIn page to learn about the services provided by Chip Reuben Medical/Scientific Writing. He received his masters in molecular biology with focus on cardiovascular pharmacology and immunology, from San Diego State.
LinkedIn: https://www.linkedin.com/in/chip-reuben-8946811

Medical Writing Open Positions

Compiled By: **Sharyn Batey, PharmD, MSPH**
Employment Coordinator, AMWA Pacific Southwest Chapter

Director, Medical Writer
Avanir Pharmaceuticals, Inc., Aliso Viejo, CA
http://job-openings.monster.com/monster/e90408f5-3251-4ed8-a03e-267de7bf5c5a?mescoid=1100049001001&jobPosition=8

Medical Writer
inVentiv Health Clinical, Catalina Foothills, AZ
http://www.indeed.com/cmp/inVentiv-Health-Clinical/jobs/Medical-Writer-a92f76ef20d3f7a3?q=medical+writing

Medical Writer
Valesta Clinical Research Solutions, Tucson, AZ
http://www.indeed.com/cmp/Valesta-Clinical-Research-Solutions/jobs/Medical-Writer-720401f3bd8fb4f9?q=medical+writing

Scientific Writer
Ambry Genetics, Aliso Viejo, CA
http://job-openings.monster.com/monster/ff5ad26e-7a8a-4f7e-8ddc-400261dc634c?mescoid=2700440001001&jobPosition=6#

Director, Medical Writer
Avanir Pharmaceuticals, Inc., Aliso Viejo, CA
http://job-openings.monster.com/monster/e90408f5-3251-4ed8-a03e-267de7bf5c5a?mescoid=1100049001001&jobPosition=21

Scientific/Medical Writer
NeoGenomics Laboratories, Aliso Viejo, CA
http://jobview.monster.com/v2/job/View?JobID=179024159&MESCOID=2700440001001&jobPosition=1

Patents Medical Writer
Ionis Pharmaceuticals, Inc, Carlsbad, CA
http://www.biospace.com/jobs/job-listing/patents-medical-writer-365208

Scientific Writer - OFIS
City of Hope, Duarte, CA
http://job-openings.monster.com/monster/724f34b9-9977-4e02-9e0e-a4289608cc57?mescoid=2700440001001&jobPosition=10

Medical Writer - Pharmaceutical
Brandkarma, Irvine, CA
http://job-openings.monster.com/monster/8af005f9-c97d-4303-b0e9-a0ce8b5b4e77?mescoid=2700440001001&jobPosition=22#

Science Writer or Science Writer/Project Manager
The Scripps Research Institute, La Jolla, CA
Contact: Erica Ollmann Saphire erica@scripps.edu

Freelance Medical/Scientific Writer
Hoag Orthopedics, Orange, CA
https://www.indeed.com/cmp/Orthopaedic-Education-and-Research-Insti/jobs/Freelance-Medical-Scientific-Writer-51de2211bde6cdb6?q=medical+writing

Medical Writer
Lotus Clinical Research, LLC, Pasadena, CA
http://www.indeed.com/cmp/Lotus-Clinical-Research,-LLC/jobs/Medical-Writer-59aec4e7f9b0493c?q=medical+writing

Director, Medical Writing
Acadia Pharmaceuticals Inc., San Diego, CA
http://job-openings.monster.com/monster/dabeaf8e-2f59-447b-aad5-bdf13097b757?mescoid=1100049001001&jobPosition=5

Associate Director, Medical Writing
BioPhase Solutions Inc, San Diego, CA
http://www.biospace.com/jobs/job-listing/associate-director-medical-writing-364820

Senior Medical Writer
Intercept Pharmaceuticals, Inc, San Diego CA
http://job-openings.monster.com/monster/9db8ae89-10e7-4931-80c7-2080efddd980?mescoid=2700440001001&jobPosition=34#

Science / Medical Proofreader (Marketing)
International Programming & Systems Inc., San Diego, CA
https://ipsamerica.com/Jobs/Info.aspx?id=4165i&id2=6&utm_source=Indeed&utm_medium=organic&utm_campaign=Indeed

Scientific/Technical Writer/Editor (Part-time)
Leidos, San Diego, CA
http://job-openings.monster.com/monster/2ee74907-aedd-46d4-a849-3df7ca5337a2?mescoid=2700440001001&jobPosition=5

Technical Editor (Contractor)
MLS Technologies, Inc, San Diego, CA
http://search4.smartsearchonline.com/receng/jobs/jobdetails.asp?current_page=2&city=&location=&job_type=&emp_status=&country=&k1=&k2=&k3=&k4=&k5=&k6=&k7=&k8=&salary_min=&co_num=&apply=yes&job_number=905&sourcename=Indeed

Medical Writing Manager or Senior Manager
Receptos, San Diego, CA
http://job-openings.monster.com/monster/a2cd0798-f6f9-474c-a31e-d92eab65099a?mescoid=1100049001001&jobPosition=6

Manager Medical Writing, Clinical Research
Abbott Laboratories, Santa Ana, CA
http://job-openings.monster.com/monster/ceb4e051-79d3-4ec2-9a84-ba4640f7d37c?mescoid=1100049001001&jobPosition=7#

Senior Specialist Scientific Communication
Abbott Laboratories, Santa Ana, CA
http://job-openings.monster.com/monster/244d0930-109f-4a70-9e3f-d93b915c0a2d?mescoid=2700438001001&jobPosition=30#

Regulatory Writing Manager
Amgen, Inc, Thousand Oaks, CA
http://job-openings.monster.com/monster/337743ad-8c41-4f63-a0b3-92e22c5a91b3?mescoid=2700439001001&jobPosition=18#

Medical Writing Manager
Amgen, Inc, Thousand Oaks, CA
http://job-openings.monster.com/monster/623eaf52-8c57-433f-b536-ef722db08403?mescoid=1100049001001&jobPosition=8#

Medical Writing Manager (Health Economics)
Amgen, Inc, Thousand Oaks, CA
http://job-openings.monster.com/monster/0383ab62-6aa0-4191-b74f-80d334ab88ff?mescoid=1100049001001&jobPosition=25#

Senior Medical Writer - Remote
MMS Holdings Inc, Thousand Oaks, CA
http://mmsholdingsinc.applytojob.com/apply/0c3b061d7e5e706c6a615c595a55030a50756f462b1124143b094219714e025f47610b/Senior-Medical-Writer-Remote?source=INDE&sid=fTdBLnAZZRnmkl63dF0tjFoXnBuJ7wUnp7Y

If you want to share job leads with the members of the Pacific Southwest Chapter, please contact Sharyn at employment-coordinator@amwa-pacsw.org.

AMWA Pacific Southwest Chapter Warmly Welcomes Our New Members

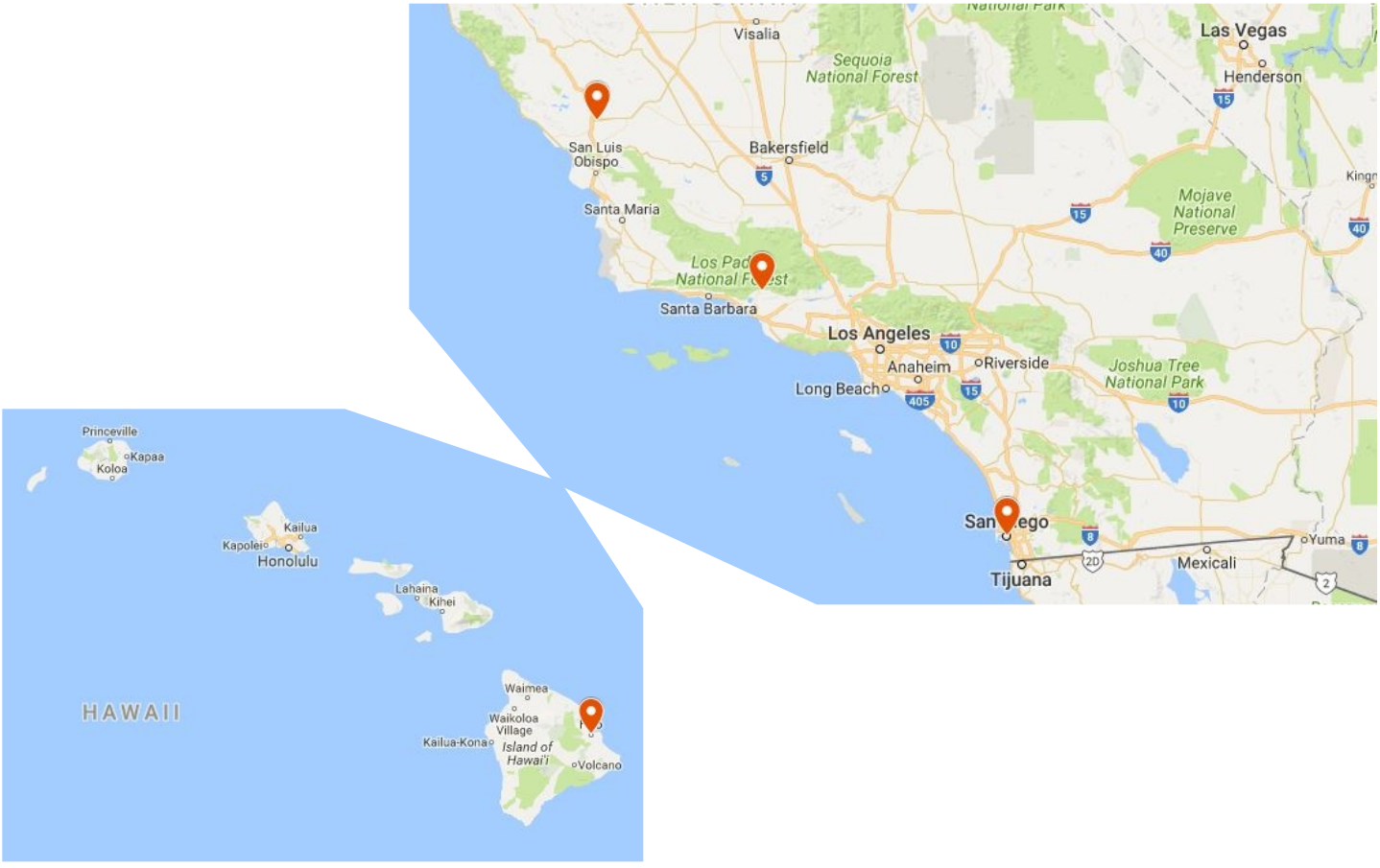
Anne Austen – Ojai, CA

Janine Siegel – San Diego, CA

Kathleen Moore – San Diego, CA

Lonnie Marcum – Paso Robles, CA

Nishant Gandhi – Hilo, HI



List courtesy of Gail Flores, PhD, AMWA Pacific Southwest Chapter membership coordinator.
Email: member-coordinator@amwa-pacsw.org

Upcoming Chapter Events

Feb 3 Mar 3 Mar 4 Apr 22

AMWA Pacific Southwest Chapter Lunch (Monthly) Teleconference
Occurs First Friday of the month, 12:00-1:00 PM Pacific time

Hosted by Donna Simcoe, Past President of the Chapter
Dial-in number: 706-913-1155
Participant code: 0204157# (or from your iPhone: 706-913-1155,0204157#)
Free. Open to members and non-members.
Next meeting: **Friday, February 03,** and **March 03, 2017**

SAVE THE DATE:

- **March 04, 2017**: Member Appreciation Event: Tea Moderno at The Resort at Pelican Hill in Newport Beach (Free for Chapter members.)
- **March 2017**: Jane Rollins will talk about her experience publishing her book on healthcare information for patients.
-

2017 AMWA CHAPTER CONFERENCE SCHEDULE

http://www.amwa.org/chpt_conferences2

Mid-Atlantic Chapter Conference
March 10, 2017. Chevy Chase, MD

Delaware Valley Chapter Freelance Conference
March 18, 2017. King of Prussia, PA

Southwest Chapter Conference
April 22, 2017. Austin, TX

Pacific Southwest Chapter Conference
April 22, 2017. Costa Mesa, CA

Indiana Chapter Conference
April 22, 2017. Indianapolis, IN

Delaware Valley Chapter presents the Princeton Conference
April 22, 2017. Princeton, NJ

Carolinas Chapter Conference
May 5, 2017. Chapel Hill, NC

What's Happening at AMWA National

What's New

AMWA-EMWA-ISMPP Joint Position Statement. Professional medical writing support helps authors and sponsors to disclose their research in peer-review journals and scientific congresses in an ethical, accurate, and timely manner, with the ultimate aim of advancing patient care. Read the full joint position statement at http://www.amwa.org//Files/JointPositionStatement.ProfessionalMedicalWriters.Jan2017.pdf

CORE Reference
AMWA partnered with EMWA to create the CORE Reference, a user manual to help medical writers navigate relevant guidelines as they create clinical study report (CSR) content. http://www.amwa.org/core

AMWA Online Learning

Visit http://www.amwa.org/online_learning

Includes On-Demand Videos (including over 25 recordings of live AMWA webinars) and Resource Documents (including Pocket Trainings and AMWA Journal Collections). Featured activities:

- FIT: Fast Interactive Training
- Unlock the Secrets to Freelance Success
- Check. Correct. Improve. Be Your Own Best Editor
- Regulatory Writing Overview: Roles, Documents, and Process
- A Career in Medical Communication: Steps to Success
- Harness the Power of EndNote
- Ten Characteristics of Effective Tables and Graphs

Regulatory Writing Overview package – Jump-start a career in regulatory writing with this three-part online learning activity. Save over 15% by purchasing all three activities as a package. Learn more at www.amwa.org/regulatory123.

A Career in Medical Communication: Steps to Success – Designed to answer the most frequently asked questions about becoming a medical writer, this online learning activity will explore what medical communicators do, where they work, and the variety of documents they produce. Explore further at www.amwa.org/careersteps.

Find these activities, archived recordings of AMWA Live Webinars, Pocket Trainings, and more in AMWA Online Learning at www.amwa.org/online_learning.

Essential Skills package

Purchase all 7 Self-Study Workbooks and earn the AMWA Essential Skills certificate at your own pace. Certificate enrollment is included.
http://www.amwa.org/es_express

Upcoming AMWA Webinars

Managing Living Literature Reviews
Feb 09, 2017, 11:00 – 12:00 pm ET
Member Complimentary

Visit the AMWA Event Calendar (http://www.amwa.org/calendar_list.asp) for a full list of upcoming events, and registration details. Most webinars are $55 for members and $95 for non-members.

AMWA 2017 Pacific Coast Conference

April 21 – 22, 2017
Crowne Plaza Hotel Costa Mesa
3131 Bristol Street
Costa Mesa, California

Half-day Intensive Training Sessions, Short Sessions,
and Provocative Conversations with Writers, Editors, Scientists,
and Other Medical Communicators

AMWA 2017 Pacific Coast Conference Program

Friday, April 21, 2017	
6:00 – 8:00 pm **Welcome Poolside Reception (registrants only)**	
Saturday, April 22, 2017	
7:30 am **Registration opens**	
8:00 – 9:00 am **Continental Breakfast and Conference Welcome**	
Intensive training Sessions (3 hours)	**Short Sessions (1.25 hours)**
9:00 – 12:00 pm **Intensive Training Session 1: The Editing Clinic: Tips for Better Editing** Marianne Mallia, ELS, MWC, Mayo Clinic, Scottsdale, AZ	9:00 – 10:15 am **Short Session 1: Regulatory Requirements and Best Practices for European Clinical Evaluation Reports (CERs). The Role of the Medical Writer.** Jim Lutz, MS, CCRA, Lutz Consulting, LLC, Buellton, CA Kim Walker, MS FRAPS, RAC (US, EU), Kim Walker Consulting, Orange County, CA
10:15 – 10:45 am **Mid-morning Break – Promenade Reception Area**	
Intensive Training Session 1 continued	10:45 – 12:00 pm **Short Session 2: What's Different About Regulatory Writing for Biologics?** Aaron Van Etten, MS, Independent Regulatory Writer, Newbury Park, CA
12:15 – 1:45 pm **Lunch (includes networking event)**	
1:45 – 4:45 pm **Intensive Training Session 2: Everything You Need to Know About MS Word and Adobe Acrobat to Prepare for FDA's Upcoming eCTD Mandates.** Antoinette Azevedo, President, eSubmission Solutions, Sage Submissions, RegDocs 365, San Diego, CA	1:45 – 3:00 pm **Short Session 3: Evaluating and Reporting Pharmacokinetic Results in Clinical Trials** Michelle Smith, MA, Merck, Omaha, NE
3:00 – 3:30 pm **Afternoon Break – Promenade Reception Area**	
Intensive Training Session 2 continued	3:30 – 4:45 pm **Short Session 4: Freelance Medical Writer Considerations (panel discussion)** Susan Vintilla-Friedman, MCW, Vintilla Communications, LLC, Carlsbad, CA Donna Simcoe, MS, MBA, CMPP, Simcoe Consultants, Inc., San Diego, CA Heather S. Oliff, PhD, Science Consulting Group, LLC, North Tustin, CA
5:30 pm **Chapter Greet-and-Go Dinner in South Coast Plaza** (pay on your own, not included in registration fee)	
8:00 pm T**heatre Outing "The Siegel", South Coast Repertory** (separate fee)	

Note: Sessions will be occurring simultaneously. Attendees have their choice of attending either an intensive training or 2 short sessions in the morning and afternoon parts of the meeting.

General Conference Information

Registration

Registration fees include poolside reception, breakfast, break refreshments and lunch. Parking is complimentary. Each short session and intensive training session has an additional charge (see last page). Guest tickets to the Friday evening reception may be purchased for $30.

Conference registration is an online process. Payments accepted include VISA, MasterCard, and American Express. Onsite registration and onsite updates to individual itinerary can only be accommodated by check or cash.

If you need to cancel your conference registration, you must send an e-mail to treasurer@amwa-pacsw.org to cancel registration and request a refund by **April 15, 2017.** Refunds will be issued through your method of payment, less a non-transferrable $25 registration cancellation fee. **No refunds are available for cancellations after April 15, 2017**. No refunds or credits will be given for failure to attend, late arrival, unattended events, or early departure.

Accommodations

The AMWA 2017 Pacific Coast Conference will take place at the Crowne Plaza Hotel (3131 Bristol Street, Costa Mesa California, 92704; http://www.cpcostamesa.com/). The hotel is ideally located close to Disneyland and Knotts Berry Farm theme parks, vibrant coastal towns, premier shops and restaurants at South Coast Plaza, and a preeminent performing arts center.

Discounted room rates ($129 per night) are available until **March 22, 2017** for Conference attendees. To make a reservation, follow this link: AMWA Pacific Coast Conference Reservations (The group code will display as "AMW"; please enter the dates of your stay and click on the "Book" button).

Travel Information

From the airport: The Crowne Plaza Hotel offers a complimentary shuttle to/from the John Wayne Orange County airport (SNA). Call the hotel Front Desk at (714) 557-3000 to request the shuttle (5:30 am to 10:30 pm).
By car: From Interstate Highway 405, take the Bristol Street exit 9B, turn West onto Bristol Street, and turn right in 141 feet into the Crowne Plaza. Free parking is available both outside and in a covered parking structure.

Theatre Outing, South Coast Repertory Theatre (separate fee)

Join us Saturday April 22, 2017 at 8 pm to attend the world premiere of "The Siegel", an irresistible comedy about modern love and the need to go back in order to move forward, at the South Coast Repertory, Orange County's Tony Award-winning theatre (http://www.scr.org/). Written by Michael Mitnick and directed by Casey Stangi, "The Siegel" is a recipient of an Edgerton Foundation New American Plays Award, granted by Theatre Communications Group, the national organization for theatre. A limited number of tickets are available at the nonrefundable group discount price of $58 and can be purchased by following this link: AMWA 2017 Pacific Coast Conference Night at the Theatre. Tickets will be distributed the evening of the performance. Free transportation from the theatre back to the hotel will be provided.

AMWA Medical Writing Certification Examination (separate fee)

The MWC™ Exam will be offered prior to the AMWA 2017 Pacific Coast Conference on **April 21, 2017** at the Crowne Plaza Hotel and will be administered by AMWA's Medical Writing Certification Commission. If you are interested in taking the exam, visit AMWA's website, http://www.amwa.org/mwc, for instructions on how to apply and register. Please note that the application deadline for this exam is **March 10, 2017**.

AMERICAN MEDICAL WRITERS ASSOCIATION Pacific Southwest Chapter

Descriptions of Short Sessions and Intensive Training

Short Session 1: Regulatory Requirements and Best Practices for European Clinical Evaluation Reports (CERs) The Role of the Medical Writer (1.25 hours)

Clinical Evaluation Reports (CERs) are a relatively new requirement for medical devices sold into the European Union (EU). Since December 2009, all medical devices, regardless of risk or classification, require a compliant CER to be available for audit. The CER is an objective and thorough assessment and analysis of clinical evidence pertaining to the device to verify its safety and performance. A CER is required to obtain a CE mark and must be periodically updated as new information becomes available. While the CER is technically a series of related documents, it is best described as a process by which these documents are generated. CER best practices are systematic and transparent reviews of clinical evidence and should be conducted in a scientific and replicable manner and follow a well-defined standard operating procedure.

This presentation is intended to provide the medical writer with a basic understanding of the regulatory framework driving the need for CERs and an overview of best practices for their generation. With the June 2016 issuance of MEDDEV 2.7.1 Rev 4 and the coming Medical Device Regulations (MDRs), there are sweeping new changes coming to the EU medical device industry which create an opportunity for medical writers, and there is currently a shortage of qualified writers with CER knowledge and experience. Jim Lutz, MS, CCRA, Lutz Consulting LLC and Kim Walker MS FRAPS, RAC, Kim Walker Consulting

Short Session 2: What's Different About Regulatory Writing for Biologics? (1.25 hours)

The presentation will summarize how biologics, particularly therapeutic proteins, are different from traditional small molecule drugs; how these differences affect the clinical programs for these products; and how these differences ultimately affect the regulatory writer's work. Examples of clinical development of therapeutic proteins will be briefly discussed. Orphan drugs, many of which are biologic therapeutics, will also be discussed. Aaron Van Etten, MS, Independent Regulatory Writer

Short Session 3: Evaluating and reporting pharmacokinetic results in clinical trials (1.25 hours)

Learning how to report PK results for trials with simple to medium-complexity PK objectives can add relevant depth to the regulatory writer's portfolio of skills. This seminar will give a high-level overview of basic PK concepts to prepare regulatory medical writers to provide appropriate interpretation and summaries of PK results. Michelle Smith, MA, Merck

Short Session 4: Freelance Medical Writer Considerations (1.25 hours)

Join a panel of freelance medical writers to discuss topics to consider if you are thinking about entering into freelance writing or already have a thriving freelance writing company. Topics will include which business structure to use including an analysis of fees/taxes for different business structures, whether to charge hourly vs flat fee rate, apps that may help freelance writers, project management skills, etc. Panel members include: Susan Vintilla-Friedman, MCW, Vintilla Communications, LLC, Donna Simcoe, MS, MBA, CMPP, Simcoe Consultants, Inc., and Heather S. Oliff, PhD, Science Consulting Group, LLC

Intensive Training Session 1: The Editing Clinic: Tips for Better Editing (3 hours)

In this interactive session, the leader will present tips that you can use to improve the editing of your own and others' documents, including some finer points of grammar and style. What you'll learn should make an immediate difference in your ability to prepare a document that is clear and concise. Group work will allow participants to practice their skills. Marianne Mallia, ELS, MWC, Editor, Mayo Clinic

Intensive Training Session 2: Everything You Need to Know About MS Word and Adobe Acrobat to Prepare for FDA's Upcoming eCTD Mandates (3 hours)

This half-day session will provide hands-on training on the use of MS Word and Adobe Acrobat for preparing documents for eCTD Submissions. FDA has mandated that all commercial DMFs, ANDAs, NDAs and BLAs must be submitted in eCTD format from May 5, 2017. Commercial INDs must be submitted in eCTD format from May 5, 2018. No exceptions will be granted from these mandates. The foundation skills for preparing eCTD submissions are found in the correct use of Microsoft Word and Adobe Acrobat to meet the PDF requirements for documents submitted in eCTD submissions.

Students who wish to participate in the hands-on training will be required to bring **a laptop computer with an RJ45 port** (i.e., no tablets).to this session. They will be provided with remote access to a cloud environment pre-configured with MS Word and Adobe Acrobat Professional, with MS Word templates optimized for eCTD PDF compliance.
Antoinette Azevedo, President e-SubmissionsSolutions.com and Sage Submissions will lead this training.

Information for this training follows:

- Students who do not wish to use a computer but would like to attend are welcome to enroll.
- Please bring a mouse for greatest efficiency for this training.
- Please assure that you have Remote Desktop Connection software running on your computer.
- **You must be able to connect your computer to RJ45 Ethernet – be advised that you may need to purchase an adaptor!** This is how you will connect to the training environment which will feature optimized performance when using an RJ45 Ethernet connection. RJ45 is a type of connector on the back or side of laptop computers required for hard-wired Ethernet connection. It looks similar to a telephone jack, but is slightly wider. iPads and tablets do not have RJ45 ports. Some of newer laptops and MacBook Pro do not have RJ45 ports. Therefore, to use these computers you must purchase an adapter that plugs into your laptop computer connect a RJ45 cable to the RJ45 port on the adapter. Here are adapters available on Amazon (https://www.amazon.com/HDE-Speed-Ethernet-Network-Adapter/dp/B009GHJOF0). Users who wish to use a MacBook Pro can go to this web site to determine if their computer can support an adapter https://support.apple.com/en-us/HT201163.

An adaptor for a PC:

For older laptops, you can plug the ethernet cable directly into the side or back of the computer:

AMERICAN MEDICAL WRITERS ASSOCIATION Pacific Southwest Chapter

AMWA 2017 Pacific Coast Conference Registration

To register for the conference, use the following link: AMWA 2017 Pacific Coast Conference Registration**.** Payment by VISA, MasterCard, or American Express accepted.

Conference Fees

	Registered by February 28, 2017		**Registered by April 15, 2017**	
Item	Member	Nonmember	Member	Nonmember
Conference Registration	$165	$195	$195	$225
Short Sessions				
Clinical Evaluation Report	$10	$15	$15	$20
What's Different About Regulatory Writing for Biologics?	$10	$15	$15	$20
Evaluating and Reporting Pharmacokinetic Results in Clinical Trials	$10	$15	$15	$20
Freelance Medical Writer Considerations	$10	$15	$15	$20
Intensive Training Sessions				
The Editing Clinic	$125	$150	$150	$175
Everything You Need to Know About MS Word and Adobe Acrobat to Prepare for FDA's Upcoming eCTD Mandates*	$125	$150	$150	$175

*Prerequisite: To participate in hands-on training, students must bring a laptop (no tablets) with ethernet connectivity (RJ-45) capability and Remote Desktop Connection software running. It may be necessary to purchase an adaptor prior to the conference (adaptors will not be provided). For more information refer to page 5. Students who do not wish to use a computer but would like to attend are welcome to enroll.

Be sure to provide your name and affiliation exactly as you want them to appear on your conference name badge. Also, please indicate if we may publish your phone number and email address in the conference syllabus.

Please also note that the lunch is buffet-style and offers vegetarian options. Gluten-free requirements can be accommodated with advance notice, please contact conference organizers.

FOR QUESTIONS PLEASE CONTACT THE CONFERENCE ORGANIZERS

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The Physics of Swirling Skies in van Gogh's "Starry Night"

Vincent van Gogh painted *Starry Night* during the last years of his life in 1889 at the time when he was suffering from an unstable mental state. In *Starry Night*, he used brushstrokes to translate the chaos in his troubled mind into swirling skies. The swirls and eddies around flickering stars in the night sky of the painting remind of eddies in jet exhaust, swirling clouds on Jupiter's moons, or eddies on water here on earth—and, similar to these physical phenomenon, van Gogh's painting also follows the physics of fluid dynamics.

In 2004, NASA/ESA Hubble telescope captured a picture of a distant star that had eddies, likely clouds of gas and dust turbulence, reminiscent of van Gogh's *Starry Night*. So a group of physicists from Mexico, Spain and UK, inspired by this connection, looked for the mathematical fingerprint of turbulence in van Gogh's painting. They found that swirls and eddies in 3 of van Gogh's paintings, all created during the years of his intense struggle with mental illness, followed the physical laws of turbulence. This mathematical signature was *not present* in paintings created during his calmer mental state (eg, *Self-Portrait with Pipe and Bandaged Ear*), or in painings by others, also with swirls, eg, Edvard Munch's *The Scream*.

Biologically, our brain uses the primitive part of visual cortex to process information about contrast and motion, and the primate subdivision for discerning contrasting colors. When layered with interpretation from the primitive brain, without blending color and contrast, the images with different colors but same brightness are perceived as flickering. Intuitively, the Impressionist-era painters developed brushstrokes that created an image of light in motion by exploiting this property of luminescence, giving a perception of flickering, pulsing, or radiating light in a viewer's mind, as in Monet's *Sunrise*. But, only van Gogh was able to depict mathematically (without knowing) turbulent flow because he faithfully re-created images from his own turbulent chaotic mind.

With his paintings, *Starry Night* (1889), *Road with Cypress and Star* (1890), and *Wheat Field with Crows* (1890), van Gogh has another unique distinction of bringing together neurobiology, art, and physics with, what else, turbulence.

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